

A self-made disposable iris retractor in small pupil phacoemulsification

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Abstract

• **AIM:** To explore a simple and low-cost self-made disposable flexible iris retractor and study its clinical efficacy and safety in small pupil phacoemulsification.

• **METHODS:** Polypropylene suture and scalp acupuncture were used to make iris retractor. A prospective study were carried on 50 patients (50 eyes) with a maximally dilated pupil size of 2.5–4.0 mm which underwent phacoemulsification using this self-made iris retractor. Another 50 cases of phacoemulsification with normal pupil size sever as control group. The mean operation time, ultrasound time and ultrasonic power, volume of irrigation fluid were documented intraoperatively. The visual acuity, pupil size and complication were observed on 1d, 1wk, 1mo and 1y after operation. Corneal endothelial cell was measured at 1mo postoperatively.

• **RESULT:** Pupils could be expanded to approximately 4.5–5.5 mm with our self-made iris retractor in operation. No serious postoperative complication was found. Most (88%) of the pupils returned round or oval shape, light reflex restored to varying degrees at the first day after surgery. Best corrected visual acuity stabilized in 37 eyes (74%) at one day, in 43 eyes (86%) at one week, in 44 eyes (88%) at one month and 46 eyes (92%) at one year. Compared with the control, more time was needed to complete the operation in the small pupil group. There was no significant difference of the mean ultrasound time, ultrasonic power, volume of irrigation fluid required

and corneal endothelial cell loss in 1mo follow up between the two groups.

• **CONCLUSION:** Our self-made disposable flexible iris retractor could be easy obtained preoperatively or intraoperatively. It performed both safety and efficacy in our clinical trials. This simple self-made device has shown economic and practical values, especially in primary care hospital of the less developed districts.

• **KEYWORDS:** small pupil; iris retractor; phacoemulsification

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INTRODUCTION

A small pupil presents a considerable challenge for cataract surgeons. Such cases carry a fairly high risk of complications such as failed capsulorhexis, posterior capsule rupture, vitreous loss, dropped nucleus, endothelial cell loss and asymmetrical IOL fixation^[1]. Small pupils are commonly caused by a lot of reasons such as central posterior synechias related to anterior uveitis, trauma, previous surgery, advance age, diabetes and pseudoexfoliation syndrome etc^[2-4].

Previously, various methods have been devised to enlarge the pupil for increased safety. Graether developed a useful device to expand the pupil^[5]. Mackool^[6] described iris retractors that have small hooks connected to small blocks of titanium that can be used without assistance to retract the iris. Chang and Campbell^[7] reported their usage of iris hooks in small pupils associated with Intraoperative floppy iris syndrome. Oetting and Omphroy^[8] modified techniques in using iris retractors to reduce the possibility of iris prolapsed as well as damage. Malyugin has proposed a new injectable iris ring useful for cataract cases with small pupils. (B. Malyugin, MD, "New Iris Ring Useful for Cataract Cases with Small Pupils and Weak Zonules," Eurotimes. Available at: iogen.fi/files/2011/10/Malyugin-Eurotimes.pdf. Accessed December 28th, 2012). Meanwhile, the device we have found most useful and commonly used, is the flexible iris retractor made from modified suture material with a plastic sleeve developed by de Juan E and Hickingbotham^[9]. This type of iris retractor has long been commercialized and been

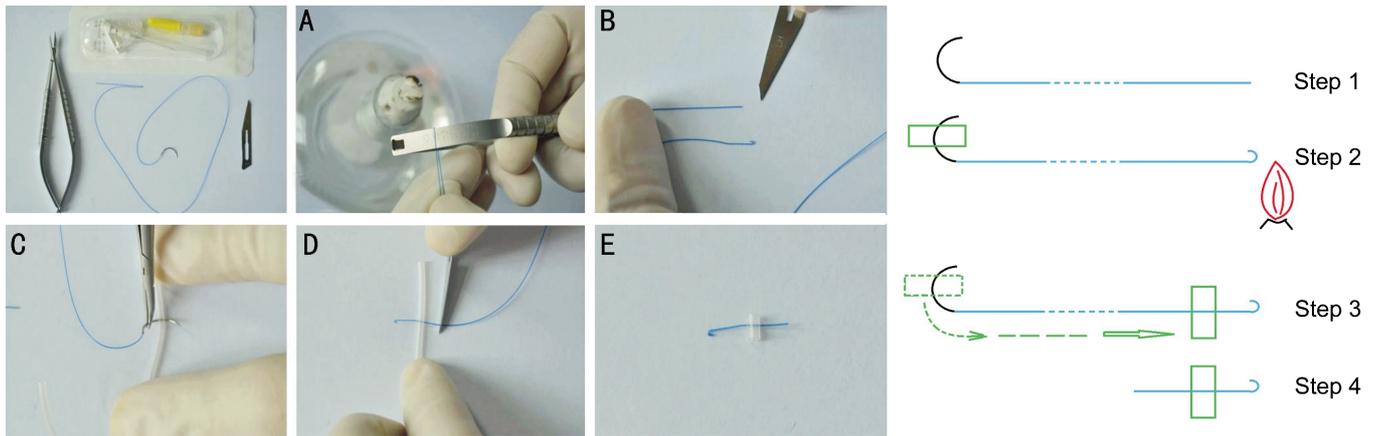


Figure 1 Simple process to make a disposable flexible iris retractor.

sold by ophthalmic instrument companies universally [10,11]. The modified and some self-made flexible iris retractor has been reported occasionally [12-14]. However, neither of them was both economic and practical enough to make them generally acceptable.

Here we develop a cheap, self-made disposable flexible iris retractor which can be easily obtained preoperatively or intraoperatively. This simple self-made device has shown economic and practical values especially in primary care hospital of the less developed districts. In addition, clinical trials have shown that it performs as well as, if not better than, conventional pupil stretching in terms of both safety and efficacy.

SUBJECTS AND METHODS

Subjects This prospective study was performed at Nanhai Hospital, Southern Medical University from November 2009 and December 2011. Fifty cases (24 males and 26 females) with pupils (between 2.5 and 4.0 mm) unresponsive to conventional pupil dilation techniques were involved as experimental group (small pupil group) in our study. Ethical approval was obtained from the Institutional Review Board and in accordance to the tenets of the Declaration of Helsinki. Informed consents from each enrolled subject were obtained following a detailed explanation of the nature, possible complications and prognosis of the study. The mean age was 59.7 ± 15.3 (SD) years old. These cases had various nucleus density (II-IV) and different ocular co-morbidities, which included anterior uveitis (16%), previous anti-glaucoma surgery (8%), diabetes (20%) and retinal detachment (2%). The best corrected visual acuity (BCVA) was between Light Perfection and 0.4. Control group (normal pupil group): 50 normal age-matched (62.3 ± 18.2 y) cases of phacoemulsification with normal pupil size were included; Nucleus density was between II to IV; the included cases had no history of other ophthalmic disease (Table 1).

Methods Polypropylene suture (ETHICON, INC. PROLENE W8558. 3-0), disposable scalp needle, alcohol lamp, microscopic needle holder, scalpel, Millennium™

Table 1 Background demographics

Parameters	Experimental group	Control	P
n	50	50	
Gender (M/F)	24/26	25/25	
Age (a)	59.7 ± 15.3	62.3 ± 18.2	0.21
Nucleus density (II)	12	9	
Nucleus density (III)	29	30	
Nucleus density (IV)	9	11	

Statistical analysis: Independent sample Student's *t*-test.

Microsurgical System (Bausch & Lomb Incorporated, USA).

Preparation of iris retractor 1) We cut the suture prolene, tied it round the handle of eye needle holder and made it fast. The "U" shape bended prolene was roasted on alcohol lamp fire temperately. The tension of prolene and its distance from fire was critical. After heating, the prolene was taken away from the flame to natural cooling. Then, a fixed "U" shape polypropylene hook was formed; 2) The plastic pipe of scalp needle was cut into 3 mm small piece which was used as plastic holder. Each piece of plastic holder was punctured by the needle of the prepared "U" shape suture prolene. The plastic holder was moved and placed 6 mm from the prolene hook; 3) Suture prolene was cut by scalpel at 12 mm from the prolene hook and an iris retractor is made.

The retractor is 12 mm in length (we call it retractor rod) and has a 0.8 mm hook at the end. The small plastic holder holds the retractor in place. N.B. scissors should not be used to cut the suture prolene, since the sharp end of the scissors cut suture prolene has a higher likelihood to break the posterior capsule rupture (Figure 1).

After packaging, they were disinfected by ethylene oxide sterilization. We usually made dozens of retractors and sub-packaged 4 retractors as a group in small ethylene oxide permeable plastic bag for sterilization. Domestic automatic ethylene oxide sterilizer (YWM200, Shenyang Longteng Electronic Ltd. Co.) was employed in our hospital. The main sterilization parameter as follows: Concentration of ethylene oxide: 800-1000 mg/L; Temperature: 55-60°C ; Humidity

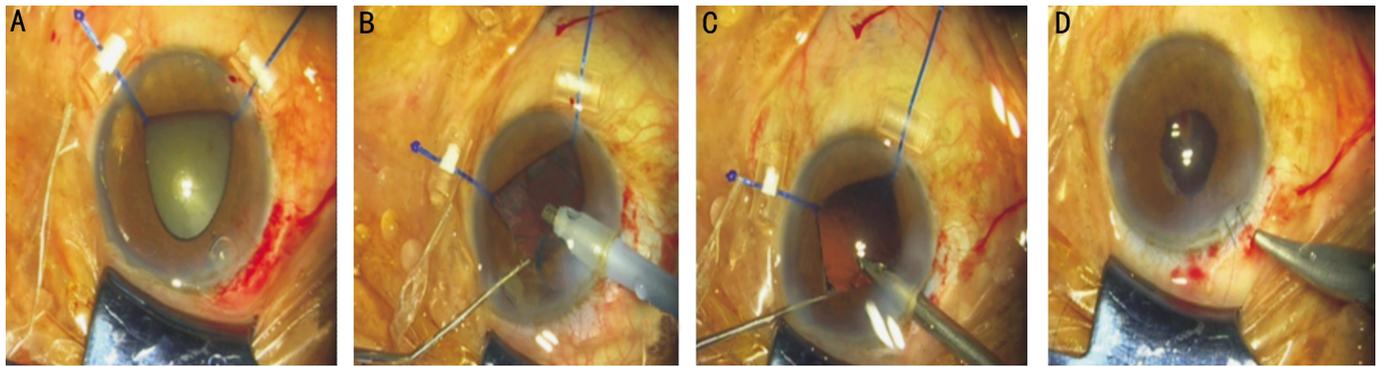


Figure 2 Clinical application of self-made iris retractor in small pupil phacoemulsification In this case, we just used 2 self-made retractors and assistant iris hook to enlarge the pupil. The enlarged pupil provides enough space for phacoemulsification (A,B,C). Postoperatively, pupil size returns to about 3 mm. The number of iris retractors used in an operation is decided by surgeon according to their experience (D).

60% -80% ; Time: 6h. Chemical indicator was used to confirm the successful disinfection process.

Surgical techniques One percent of tropicamide, 10% phenylephrine, and 0.1% diclofenac drops were given 4 times in the hour before surgery to dilate the pupil and stabilize the blood-aqueous barrier. Four areas for the wound which on the peripheral cornea were marked 90 degrees from each other. A paracentesis was made in a comfortable position for insertion of the second instrument. Two to four additional stab incisions were made by a 15 degree blade at the marked sites for the iris hooks. The self-made iris retractors were then placed as described by de Juan E and Hickingbotham [9]. Once the retractor has been inserted into the anterior chamber, the needle holder was then turned so that the retractor can hook the edge of the iris and pull it toward the entry site. The plastic holder could then be adjusted to the appropriate length and tension. With the iris retractors in position, viscoelastic material was used to displace aqueous from the anterior chamber and stiffen the eye before the corneal incision was made. The clear corneal incision was made approximately 0.5-1.0 mm anterior to the limbus. The hooks were adjusted in position again if necessary, creating a square, triangle or "D"-shaped pupil which afford enough space for phacoemulsification. The remainder of the procedure was performed in a standard fashion. The phaco tip easily glided by the retractor as the retractor was flexible and tends to bend out of the way. At the conclusion of the case, there were two ways to remove the retractor. The first one was accomplished as describe by de Juan E and Hickingbotham [9] that retractor were pulled out directly. When the hooked portion of the retractor came close to the corneal incision, it would bend and slip out; the other one was that we could remove the plastic holder first, and cut the extraocular portion of retractor rod. Then the intraocular portion was dragged out though the corneal incision. Sometimes, viscoelastic material was needed in this procedure to prevent posterior capsular rupture (Figure 2).

Generally, as to how many iris retractors should be used in an operation, the decisions were made on a 'case by case' basis by surgeon according to their experience. The mean operation time, ultrasound time and power, volume of irrigation fluid were documented intraoperatively.

Postoperative care and follow-up Postoperatively, a topical mixture of antibiotic and steroid eye drops for 2wk were prescribed. Follow-up reviews were 1d, 1wk, 1mo and 1y after operation. The visual acuity, pupil size and complication were observed. Corneal endothelial cell was measured at 1mo postoperatively.

Statistical Analysis All statistical analysis was performed with analytical software (SPSS 13.0 program; SPSS, Chicago, IL, USA). All data are presented as mean \pm SD. Statistical analysis was performed by independent sample Student's *t*-test, $P < 0.05$ was considered as statistically significant in all tests.

RESULTS

In experimental group, pupils could be expanded to approximately 4.5-5.5 mm with 2-4 self-made iris retractors in operation. The mean time for placement of self-made iris retractor was 3.2min, the mean operation time was 27.5min, the mean ultrasound time was 17.4s and the mean ultrasonic power used was 18.4%. The mean volume of irrigation fluid required was 102.3 mL. Compared with the control group, only the mean operation time significantly increased ($t=2.38$, $P < 0.05$, Table 2). No serious postoperative complication was found. There were only a few minor surgical complications included minute sphincter tears in 2 eyes (4%), a transitory increase in intraocular pressure in four eyes (8%), and micro-hyphaema in one eye (2%). The endothelial cell loss at 1mo follow-up was comparable to that observed in control group ($t=1.38$, $P > 0.05$, Table 3). Frequently, some mild increase in inflammation, manifested by increased flare and cells in the anterior chamber, was observed on the first postoperative day as conventional management of small pupils (32 eyes, 64%). The inflammatory response was related

Table 2 Operation parameters

Parameters	Experimental group (n=50)	Control (n=50)	P
Time used for placement of iris retractor (min)	3.2±0.5	0	
Operation time (min)	27.5±5.4	22.3±3.8	0.027 ¹
Ultrasound time (s)	17.4±4.3	18.2±5.6	0.15
Ultrasonic power (%)	18.4±6.9	16.5±5.8	0.28
Volume of irrigation fluid (mL)	102.3±23.5	98.4±19.5	0.21

Statistical analysis: Independent sample Student's *t*-test; ¹P considered statistically significant if value < 0.05.

Table 3 Corneal endothelial cell loss postoperatively in subjects

Groups	Corneal endothelial cell density (cell/mm ²)			P
	Preop.	1mo postop.	Mean loss	
Experimental group	2775±496	2398±424	377±116	0.14
Control group	2701±436	2375±398	326±125	

Statistical analysis: Independent sample Student's *t*-test.

to iris manipulation and responded promptly to topical steroids. Most (44 eyes, 88%) of the pupils size returned to 3-4 mm (round or oval shape) at the first day after surgery and remained stable in follow-up. Light reflex restored to varying degrees. Visual rehabilitation was also rapid in most eyes. BCVA stabilized in 37 eyes (74%) at one day, in 43 eyes (86%) at one week, in 44 eyes (88%) at one month and 46 eyes (92%) at one year.

DISCUSSION

A small pupil is undesirable for cataract and vitreoretinal surgery. Several methods have been developed to enlarge a small pupil intraoperatively. Flexible iris hooks has been introduced by de Juan E and Hickingbotham and Nichamin [9,15]. The use of flexible iris hooks for cataract surgery continues to be refined and commercialized. In our study, we develop a simple and low-cost self-made iris retractor.

We have used our self-made iris retractor in 50 cases with small pupils unresponsive to conventional pupil dilation techniques. No serious postoperative complications were found. There were only minor surgical complications included minute sphincter tears, a transitory IOP increase, and one case of micro-hyphaema. Compared with the control, the operation time of small pupil group seemed longer. But the extension of operation time mainly related to the placement of iris retractor rather than operation itself. There was no significant difference of the mean ultrasound time, ultrasonic power, volume of irrigation fluid required. The endothelial cell loss was comparable to that of control group at 1mo postoperatively. Mild increase in inflammation related to iris manipulation responded promptly to topical steroids. Visual rehabilitation was also rapid in most eyes. We didn't present the exact postoperative BCVA of both groups but the stabilization time of it. Actually, the postoperative average BCVA of small pupil group was relatively lower than that of the control group. This was reasonable since postoperative BCVA of eyes in small pupil

group was affected by other ocular co-morbidities such as anterior uveitis, previous anti-glaucoma surgery, diabetes *etc*. Pupil size of 44 eyes (88%) returned to 3-4 mm at the first day after surgery and 2 eyes (4%) had minute sphincter tears. The rest 4 eyes (8%) could not recover its round shape, showing irregularities in pupil border without visible damage or abnormality. Dr. Tognetto reported a clinicopathological case of ocular surgery required iris hook dilation [16]. Indeed, iris retractors cause damage to the iris structure at the point at which the iris retractors are positioned. According to the iris sections, the sphincter muscle appeared thinner, granulous degeneration was evident in the deeper layers of iris, and the vessels presented mild hyalinosis of the walls. These could explain why other 8% pupils could not return to normal size even though no visible abnormality was found. Most likely, their inner structures were slightly damaged and the function of sphincter papillae was decreased. However, in our experience, regular recover of the pupil size could result from the devices more gently stretching of the iris tissues. In a word, our self-made iris retractor showed a good safety in cataract surgery. In addition, to achieve optimal pupil size, the number of self-made iris retractor employed in a surgery should be decided by the surgeon regarding the particular condition and his/her experiences [17]. Frankly, the aim of the study at first was to prove this self-made retractor rod is practicable and safe. We have not conducted a well-controlled study to comparing the commercially available retractor with our self-made retractor rod about their clinical parameters such as complication rates, surgery and implantation time *etc*. Since its mechanism and usage are similar to the previously reported mainstream iris retractor, the clinical parameters mentioned above couldn't be far from each other. And this has been manifested by our observation in daily medical practice. However, based on rigorous attitude, a better controlled research is needed in the future.

Just like those commercialized product, our self-made iris retractor is strong enough to break even firmly adherent synechiae and enlarge pupil size yet flexible enough to prevent damage to the anterior capsule in phakic eyes. However, our self-made iris retractor can be easily and quickly made preoperatively. Furthermore, this kind of retractor can be quickly made intraoperatively if necessary in

A new self-made iris retractor

Table 4 Price of commercially available disposable iris retractor

Company	Type	Country	Price (\$)
Rumex International Co.	10-5067-6	USA	19.97
OASIS Medical, Inc.	Product # 4465	USA	18.83
Medetz Surgical Instruments	XMI-885-D25	USA	12.56
MD Purchase	MPD 112	USA	15.6
BINO SCIENTIFIC	Iris retractor	India	10.0
Self-made iris retractor			0.6–0.8

Accessed: December 28th, 2012.

some emergency. According to our experience, one polypropylene suture can be cut into 40–45 retractors which cost less than one USD per retractor. When compare with the commercially available iris retractor, which cost between 10.0 to 19.97 USD per retractor (It would be more expensive for us to buy import retractor when take tariff and shipment into account), our self-made retractor is much cheaper (Table 4). This low-cost retractor is especially suitable for the primary care hospital of the less developed districts such as those densely populated rural area in China and India. In addition, the procedure to develop our self-made retractor has shown easy acceptability and simplicity. Meanwhile, our clinical trials have shown that it performs both safety and efficacy.

In conclusion, this simple self-made disposable flexible iris retractor is practical and low-cost ophthalmic surgical instrument which would benefits primary hospital in some undeveloped areas. It can be easy obtained preoperatively and intraoperatively if necessary.

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Conflicts of Interest: Li J, None; Liu F, None; Zhang WW, None; Zhang JJ, None.

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